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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/997,872      | 11/29/2001  | Luiz B. Da Silva     | IL-10888            | 6745             |

7590 01/25/2005

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| EXAMINER                 |              |
|--------------------------|--------------|
| MANTIS MERCADER, ELENI M |              |
| ART UNIT                 | PAPER NUMBER |

3737

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

|                              |  |  |  |
|------------------------------|--|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/997,872     | <b>Applicant(s)</b><br>DA SILVA ET AL. |  |
|                              | <b>Examiner</b><br>Eleni Mantis Mercader | <b>Art Unit</b><br>3737                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 8-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-3 and 8-11 have been considered. While the amendment to the claims does overcome the 112/101 rejection regarding the tissue characterization aspect as previously raised the claims are still inoperative and not-enabling because of the lack of certain essential elements from the claims as explained below.

### ***Specification***

2. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is not clear how claim 2 is further limiting as the laser can only produce an optical emission signal. Appropriate correction is required.

3. The attempt to incorporate subject matter into this application by reference to 09/xxx,xxx in page 11 of the current application is improper because applications for patents are confidential and hence cannot be incorporated by reference.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the splitter(s) and the

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interconnecting optical fibers including the emission and reference optical fibers and the optical fibers associated with the detectors.

6. Claims 1-3 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the interrelations between the optical fibers connecting the emission, the reference and the detector optical fibers.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The splitters 33 and/or 50 and 52 and the optical fibers are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In the specification there are two different embodiments reflected by Figures 2 and 3, having a single splitter 34 or two splitters 50 and 52, respectively, which are essential for the generation of the emission and the reference signal, which are not claimed. In addition optical fibers, which are required for the invention including the emission and reference optical fibers and the optical fibers associated with the detectors which are also not claimed. All these features and their interrelationships must be claimed especially in view of the use of the transitional language "consisting" since the claims would not be enabling in the absence of such features. Note that

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claim 8 includes only a single splitter, which is described and is described as splitting the emission signal and the reference signal instead of splitting the laser output into the emission signal and the reference signal. Furthermore as previously stated, the features are essential and must be claimed in the independent claim.

*Claim Rejections - 35 USC § 101*

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 1-3 and 8-11 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. In the specification there are two different embodiments reflected by Figures 2 and 3, having a single splitter 34 or two splitters 50 and 52, respectively, which are essential for the generation of the emission and the reference signal, which are not claimed. In addition optical fibers, which are required for the invention including the emission and reference optical fibers and the optical fibers associated with the detectors are not claimed.

All these features and their interrelationships must be claimed especially in view of the use of the transitional language “consisting” since the claims would not be operable in the absence of such features. Note that claim 8 includes only a single splitter, which is described and is described as splitting the emission signal and the reference signal instead of splitting the laser output into the emission signal and the reference signal. Furthermore as previously stated, the features are essential and must be claimed in the independent claim.

11. Claims 1-3 and 8-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In claim 1, line 6, the use of the terminology “a needle


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that is inserted into the tissue" inferentially claims the human body. The Examiner suggests changing the language to --a needle that is **adapted to be** inserted into the tissue--.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is (571) 272-4740. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Eleni Mantis Mercader  
Primary Examiner  
Art Unit 3737

EMM